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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | KARPINSKI, LUKE E |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| | | | |
|------------------------------|------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/562,639 | TUNGUY-DESMARAIS, PETER | |
| | Examiner | Art Unit | |
| | LUKE E. KARPINSKI | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 September 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 and 7 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 and 7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Receipt of arguments, remarks, and amendments filed 9/26/2008 is acknowledged.

Claims

Claims 6, 8, and 9 are canceled.

Claims 1-5 and 7 are currently pending and under consideration in this action.

It is noted by the examiner that under the 'dependant claims' heading on page 11 of 12 of the remarks/arguments filed by applicant on 9/26/2008, applicant asserts that claims 11-15 are added to set forth additional novel features on the invention, yet the set of claims filed 9/26/2008 shows no new claims.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claims 1, 2, and 7 to recite *Melaleuca dissitiflora* and *Melaleuca linariiflora*. Neither of these plant species were recited in the specification or claims as filed. Although applicant does recite 'tea tree', the applicant defines 'tea tree' on page 4 of the instant specification "...the Tea Tree oil is used as the essential oil of *Melaleuca alternifolia*..." This definition reads as tea tree oil is the essential oil of *Melaleuca alternifolia* and no other species of tea tree, therefore there is no support for applicant to add additional species of tea tree, including *Melaleuca dissitiflora* and *Melaleuca linariiflora*. Claims 3-5 are rejected for being dependant from a rejected claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, applicant claims a composition comprising a water repellent/resistant agent and an antimicrobial agent and, within the same claims, also claims said compositions consisting of only the water resistant/repellant agent and the antimicrobial agent. It is unclear if applicant is claiming a composition comprising of said elements or consisting of said elements. Claims 3-5 are rejected for being dependant on a rejected claim.

Claims 1-5 are further rejected under 35 U.S.C. 112, second paragraph, for the following reason. Claims 1 and 2 are read as a composition comprising 1) a water resistant/repellant agent 2) an antimicrobial agent in 3) a film-forming liquid. Claims 1 and 2 further recite a composition consisting of 1) a water resistant/repellant agent 2) an antimicrobial agent. It is unclear if applicant is claiming a 2 component system or a 3 component system. For the purposes of a compact prosecution the claims will be examined as a 2 component system.

Claims 1 recites the limitation "repellent" in the second to last line in said claim. There is insufficient antecedent basis for this limitation in the claim. It is assumed that the water repellent agent and the water resistant agent are one in the same and the claims will be examined as such, however, applicant is required to correct the issue.

The term "broad range" in claim 5 is a relative term which renders the claim indefinite. The term "broad range" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is well known in the art that not all anti-microbial agents work on all bacteria, fungus, or other microbes and one of ordinary skill would not be apprised of the kind or scope of the microbial agents which said anti-microbial agent is effective against.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB Patent Publication 965,236 to P. Beiersdorf and Co. A.G., herein referred to as '236, in view of US Patent No. 4,073,937 to Van Cleave and US Patent No. 6,387,382 to Saleh et al.

Applicant Claims

Applicant claims a method of treating water related outer ear disorder comprising application of a composition consisting of a film-forming agent and an antimicrobial agent, wherein said antimicrobial agent is an essential oil of melaleuca alternifolia.

Applicant further claims said composition, said film-forming agent as a silicone polymer, specifically a polysiloxane, and said antimicrobial as a broad range antimicrobial, specifically the essential oil of melaleuca alternifolia.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The '236 patent teaches compositions for application to the skin consisting of a polysiloxane and an anti-bacterial (page 2, left column, lines 33-39) as claimed in claims 1, 2, 4, and 7. Said paragraph reads that said compositions contain polysiloxanes and anti-bacterials and that said compositions **MAY** contain other components, this reads on a composition consisting of only polysiloxane and an anti-bacterial.

The '236 patent also teaches that said compositions form a film, which reads on the film-forming composition of claim 3 (page 2 right column).

It is noted by the examiner that polysiloxane reads on water repellent, water resistant, and film-forming agent.

***Ascertainment of the Difference between Scope the Prior Art and the Claims
(MPEP §2141.012)***

The '236 patent does not teach methods of treating an ear or application of said compositions to the ear canal as claimed in claim 1. This deficiency in '236 is cured by Van Cleave. Van Cleave teaches the utilization of similar compositions comprising a film-forming agent and an anti-microbial agent (col. 4 and 5) for the treatment of swimmers ear (abstract).

Further, '236 does not teach said anti-microbial as tea tree oil or melaleuca alternifolia as claimed in claims 1, 2, and 7. This deficiency is cured by Saleh et al. Saleh et al. teach tea tree/melaleuca alternifolia oil as an antibacterial known to be utilized in topical skin formulations (col. 7, lines 54-65).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

Regarding claim 1, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the formulations of '236 to treat outer ear disorders as taught by Van Cleave in order to produce the invention of instant claim 1.

One of ordinary skill in the art would have been motivated to do this because '236 teaches compositions consisting of a film-forming agent and an anti-microbial agent utilized to inhibit liquid from remaining in contact with the skin and causing bacterial to form and Van Cleave teach similar compositions which also keep liquids from remaining on the skin and causing bacterial growth, comprising film-forming agents and antimicrobials, for the preventative treatment of swimmers ear. Therefore it would have been obvious to utilize the ear treatment methods of Van Cleave, with the formulations of '236 in order to inhibit water or sweat from remaining on the skin and causing bacterial growth.

Regarding the limitation of tea tree oil as said antimicrobial, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of '236 with tea tree oil as said antimicrobial as taught by Saleh et al. in order to produce the invention of instant claims 1, 2, and 7.

One of ordinary skill in the art would have been motivated to do this because '236 teaches formulations consisting of a water resistant/repellant agent and an antimicrobial agent and Saleh et al. teaches water-proof skin barriers comprising tea tree oil as an antimicrobial. Therefore it would have been obvious to utilize the tea tree oil of Saleh et al., with the formulations of '236 in order to produce a topical skin barrier formulation comprising a known antimicrobial agent.

Regarding the limitation of the use of said compositions in claims 2-5 and 7. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding the limitation of said compositions being applied in droplet form, the formulations of '236 are taught in different forms, including liquid spray formulations, which would necessarily be capable of being applied in droplet form.

Regarding claim 5, Saleh et al. teach the same antimicrobial and therefore would necessarily meet the limitation of acting against a broad range of bacterial and fungal infections.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,073,937 to Van Cleave in view of US Patent No. 6,387,382 to Saleh et al. and US Patent No. 7,022,135 to Zilla et al.

Applicant Claims

Applicant claims are delineated above.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Van Cleave teaches a preventative treatment for swimmers ear comprising the application of a composition comprising a film-forming agent, which reads on a water resistant/repellant agent, and an antibacterial, which reads on an antimicrobial (abstract, and col. 4, lines 18-65) as claimed in claims 1, 2, and 7.

Van Cleave further teaches said compositions being applied with a dropper, which reads on droplet form (figure 4) as claimed in claims 2 and 7, that said formulations may comprise only the two components (col. 5, lines 57-67), and said water repellent/resistant agent as a polyoxyethylene (col. 4, line 50 to col. 5, line 56).

It is noted by the examiner that polyoxyethylene reads on water repellent, water resistant, and film-forming agent and is a synonym for polyethylene glycol (PEG).

Van Cleave also teaches that said compositions, when applied, form a coat of said composition onto the external ear canal, which remains for a specified period, which reads on said composition being film-forming (col. 4, lines 45-50).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Van Cleave does not teach said antimicrobial as tea tree oil as claimed in claims 1, 2, and 7. This deficiency in Van Cleave is cured by Saleh et al. Saleh et al. teach treating skin pathologies with water-proof skin barriers comprising water repellent/resistant agents and antimicrobial agents, specifically tea tree oil (abstract and col. 7, line(s) 55-65).

Further, Van Cleave does not teach said water repellent/resistant agent as a polysiloxane as claimed in claims 4 and 7. This deficiency is cured by Zilla et al. Zilla et al. teach both polyethylene glycols and polysiloxane as film-forming agents (claim 26).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding claims 1, 2, and 7, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Van Cleave with tea tree oil as the antimicrobial as taught by Saleh et al. in order to produce the invention of instant claim(s) 1, 2, and 7.

One of ordinary skill in the art would have been motivated to do this because Van Cleave teach similar compositions both utilized to provide skin barriers and both comprising antimicrobials and Saleh et al. teach that tea tree oil is a possible antimicrobial which can be utilized. Therefore it would have been obvious to utilize the tea tree oil of Saleh et al., with the formulations of Van Cleave in order to utilize an antimicrobial which is known to be utilized in compositions for forming water resistant barriers on the skin.

Regarding claims 4 and 7, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Van Cleave with a polysiloxane as the water repellent/resistant as taught by Zilla et al. in order to produce the invention of instant claims 4 and 7.

One of ordinary skill in the art would have been motivated to do this because Van Cleave teaches said water resistant agent as a polyoxyethylene, or polyethylene glycol, and Zilla et al. teach that both polyethylene glycol and polysiloxanes are known to be utilized as film-formers. Further, it would have been obvious to one of ordinary skill in the art to produce the formulations of Van Cleave with any film forming polymer that is known to be utilized to form a film on the skin. Therefore it would have been obvious to utilize the polysiloxanes of Zilla et al., with the formulations of Van Cleave in order to utilize a known film-forming agent within said compositions.

Regarding claim 5, Saleh et al. teach the same antimicrobial and therefore would necessarily meet the limitation of acting against a broad range of bacterial and fungal infections.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to claims 1-5 and 7 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 6, 8, and 9 have been canceled.

Claims 1-5 and 7 are rejected.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Mina Haghigian/
Primary Examiner, Art Unit 1616

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